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No. 15-1189

IN THE
Supreme Court of the United States

IMPRESSION PRODUCTS, INC.,

Petitioner,

v.

LEXMARK INTERNATIONAL, INC.,

Respondent.

On Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit

BRIEF OF *AMICUS CURIAE* MEDICAL DEVICE MANUFACTURERS ASSOCIATION IN SUPPORT OF RESPONDENT

PAUL A. STEWART,
Counsel of Record
JOSEPH S. CIANFRANI
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
(949) 760-0404
paul.stewart@knobbe.com
joe.cianfrani@knobbe.com
Attorneys for Amicus Curiae
Medical Device Manufacturers Association

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I. STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Medical Device Manufacturers Association ("MDMA") is a national trade association based in Washington, D.C., providing educational and advocacy assistance to innovative and entrepreneurial medical technology companies.[1] Since 1992, the MDMA has been the voice for smaller companies, playing a proactive role in helping to shape policies that impact medical device innovators. The MDMA's mission is to promote public health and improve patient care through the advocacy of innovative, research-driven medical device technology.

II. SUMMARY OF THE ARGUMENT

Amicus MDMA submits this brief in support of Respondent to address whether a user of a patented product that was purchased subject to specified conditions on the use of that patented product may violate those conditions without infringing the patent owner's rights.

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[1] This brief is filed with the consent of both parties. Consent was received from counsel for Respondent on December 20, 2016 and counsel for Petitioner provided consent on February 13, 2017. In accordance with Rules of the Supreme Court of the United States 37(6), MDMA states that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money intended to fund preparing or submitting this brief; and no person, other than the *amicus curiae* or its counsel, contributed money that was intended to fund preparing or submitting this brief.

This Court's decision will affect technologies and products well beyond the refurbished printer cartridges at issue in the present case. Many medical devices are designed, labelled, and expressly sold as "single-use only" for reasons of product efficacy, patient safety and to meet specific FDA requirements. Medical device manufacturers have relied for decades on the conditional-sale doctrine to aid them in ensuring compliance with performance and safety-related conditions they place on the use of their patented devices.

Petitioner Impression Products and other *amici* have suggested that post-sale restrictions are intended merely to enhance the profitability of a patented product to the detriment of downstream purchasers. This argument ignores the patient safety purpose of single-use restrictions in the medical device field. By restricting a grant of patent rights to a single use, medical device manufacturers are able to enforce their patent rights against third party refurbishers with whom they have no contractual relationships.

Quanta, as well as prior decisions of this Court, are fully consistent with single-use restrictions imposed by patentees. The exhaustion doctrine is merely a default legal rule that parties to the sale of a patented product are free to contract around, within the limits of antitrust and misuse law. The courts have consistently recognized that patentees may grant as many or as few of their patent rights as they desire, so long as the patentee does not enlarge its market power beyond the proper scope of its patent rights. Despite calls from

numerous *amici* in *Quanta*, including the United States, to prohibit post-sale restrictions, this Court declined.

Amicus MDMA also responds to arguments from *amici* supporting the Petitioner, and their view that this Court should abandon the reasoning permitting single-use restrictions in order to preserve the economic interests of reprocessing and refurbishing businesses. Arguments predicting the downfall of repair and reconditioning businesses ignore that the conditional-sale doctrine applies only to those patented products containing an express limitation of the implied license attending the sale of the patented product. Given the enormous financial success of the reprocessing industry, the number of products implicated by the conditional-sale doctrine appears to be relatively small, particularly in light of the long history of permitting and enforcing single-use restrictions.

Finally, *Amicus* MDMA respectfully submits that *Quanta* did not overrule the fundamental concept that patent owners may restrict the patent rights conveyed with a sale of a patented product, as long as the patentee does not impermissibly extend the scope of its patent rights. Accordingly, this Court should affirm the Federal Circuit's holding that single-use restrictions are consistent with this Court's precedent.

III. ARGUMENT

A. Single-Use Restrictions On Medical Devices Protect Patient Safety

Medical device manufacturers provide patients and clinicians with access to life-saving medical technologies. Their research and development efforts create innovative technologies and improve existing medical technologies to achieve better patient care. One important technological improvement is the single-use device, which arose in response to patient safety concerns. A single-use device is a medical device designed by the manufacturer for use in a single medical procedure on a single patient, and is intended to be discarded after the procedure.[2] Prior to the 1980s, medical devices were typically reusable.[3] The shape, design, and size of these medical devices, and the fact that the devices were made of materials capable of being sterilized through relatively simple processes, made these devices suitable for multiple uses.[4]

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[2] A.W. van Drongelen, National Institute for Public Health and the Environment (RIVM), *Reprocessing of Medical Devices: Possibilities and Limiting Factors*, at 7 (2008), http://www.rivm.nl/dsresource?objectid=3f8793eb-2e88-41b5-a3cb-3991a6984ec1&type=org&disposition=inline.

[3] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), *The Safety of Reprocessed Medical Devices Marketed for Single-Use*, at 8 (European Commission April 15, 2010), http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_027.pdf.

[4] *Id.*

Single-use devices arose in response to a heightened awareness of risk from infectious disease transmissions, potentially spread through reusing contaminated syringes and other medical devices that contact a patient's skin or bodily fluids.[5] Technological manufacturing improvements also led to the development of more sophisticated and complex medical devices. For example, new devices developed for minimally-invasive procedures have smaller lumens and more intricate, delicate working mechanisms that can be difficult to clean or sterilize properly.[6] Some new devices are made with less expensive materials to reduce cost, or novel lightweight plastics unable to withstand high-temperature steam sterilization processes.[7] In some cases, the FDA has required a single-use designation.[8] As a result, manufacturers have

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[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] U.S. Food & Drug Admin., *Quality Ssytem Regulation Labeling Requirements (2005)*, https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/devicelabeling/qualitysystemregulationlabelingrequirements/default.htm ("In the case of single-use sterile devices, some manufacturers include labeling to advise against resterilization and reuse. Some devices are simply not designed or constructed to be recleaned, and may not be capable of withstanding the necessary recleaning and resterilization procedures.")

labeled those devices which they determined cannot be safely reconditioned as "single-use only."[9]

Reusable medical devices designed to be reprocessed are generally manufactured so the device can be completely disassembled and thoroughly cleaned.[10] Manufacturers of reusable devices provide information on proper cleaning agents and procedures, instructions for assembly and disassembly, and appropriate water treatment exposure, to ensure proper reprocessing.[11]

In contrast, with single-use devices, third-party reprocessors may not have the information necessary to reprocess the devices in a manner that will ensure continued patient health and safety. Original manufacturers are not required to provide reprocessors with information regarding the procedures necessary to safely reprocess single-use devices.[12] General procedures for reconditioning and determining the integrity and functionality of single-use devices may not take into account the numerous variables which can affect the viability of a specific

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[9] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), *supra*, at 8

[10] Michelle R. Tinkham, *Reprocessing of Single-Use Devices: Do the Benefits Outweigh the Potential Dangers?*, 5 Perioperative Nursing Clinics 377, 379 (2010).

[11] *Id.*; Francesco Tessarolo et al., *Critical Issues in Reprocessing Single-Use Medical Devices for Interventional Cardiology*, Biomedical Engineering, Trends, Research and Technologies 619, 626 (Malgorzata Komorowska & Sylwia Olsztynska-Janus eds., 2011).

[12] Tessarolo, at 626–27.

reprocessed device.[13] For example, proper cleaning and disinfection of catheters, as well as determining a catheter's structural integrity and functionality, depend on the particular design and the materials used, and therefore vary between different catheters.[14]

Some reprocessed single-use devices may contain contaminants and exhibit reduced quality because the devices were not designed to be reconditioned or reused.[15] Single-use devices are commonly made of plastic to increase flexibility and ease of manufacturing complex designs and to lower costs.[16] New plastic single-use devices are sufficiently durable and accurate for a single use, as intended—but if a plastic device is reprocessed and reused multiple times, the device may be

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[13] *See* Tessarolo, at 622; Peter J. Goss, *Beyond the "Yuck Factor": Product Liability Implications of Medical Device Reprocessing* 7–8 (Washington Legal Foundation Working Paper Series No. 141, Sept. 2006).

[14] Tessarolo, *supra* at 622.

[15] Peter Heeg et al., *Decontaminated Single-Use Devices: An Oxymoron that May Be Placing Patients at Risk for Cross-Contamination*, 22 Infection Control & Hosp. Epidemiology 542, 542 (2001); *see also* Monica Valero da Silva et al., *Safety Evaluation of Single-Use Medical Devices after Submission to Simulated Reutilization Cycles*, 88 J. AOAC Int'l. 823, 828 (2005) ("The imperfections on [single-use device] surfaces observed through SEM [scanning electron microscopy], as well as the presence of *Bacillus subtilis* spore agglomerates and with the microbiological tests results puts into serious questioning the safety of reprocessed medical devices fabricated for 'single use only.'").

[16] van Drongelen, *supra* at 11.

unknowingly compromised.[17] Damage to single-use devices may also occur because the materials or design of a single-use device cannot withstand cleaning and sterilization processes.[18] Finally, testing reprocessed devices may fail to expose devices in which reprocessing resulted in decreased performance.[19] Some single-use devices, such as catheters, have complex designs, making it difficult to predict performance or failure of a particular reprocessed catheter.[20]

Accordingly, a blanket rule that all single-use restrictions may be violated without any consequence under the patent laws will not merely affect the profitability of printer cartridges, but will also affect the ability of medical device manufacturers to ensure

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[17] *Id.*

[18] *Id.*

[19] *See* Eucomed Med. Tech., *Eucomed White Paper on the Reuse of Single Use Devices*, at 13, 37, 40 (Dec. 15, 2009), http://www.medtecheurope.org/sites/default/files/resource_items/files/15122009_MTE_Eucomed%20White%20Paper%20on%20the%20reuse%20of%20single%20use%20devices_Backgrounder.pdf (finding no statistically significant differences in mechanical testing between new and reprocessed harmonic scalpels, but finding that *in vivo* mechanical testing demonstrated significantly decreased performance for reprocessed harmonic scalpels compared with new harmonic scalpels in terms of hemostasis).

[20] *Id.* at 37 ("Another challenge when reusing catheters is that it is difficult to predict when a catheter will degrade to a degree that it will break. When and if depends on the type of polymer used and how it is manufactured. While some plastics degrade over time and show signs of wear others seem to fail spontaneously.").

compliance with safety-based single-use restrictions. At least in the context of medical devices, the single-use restriction is an important tool for protecting public health.

B. Patent Infringement Claims Are An Essential Tool For Ensuring Compliance With Single-Use Restrictions On Medical Devices

Various *amici* argue that contract law, not patent law, is the appropriate vehicle for enforcing post-sale restrictions.[21] Although contract remedies may be available against the original purchasers of the product that agreed to the contractual restriction (and thereby presumably paid a price reflecting the reduced value of the product due to the use limitation), contract law is largely ineffective in enforcing these contractual restrictions against subsequent users who were not parties to the original contract containing the restriction.[22]

Medical device manufacturers typically sell their products directly to hospitals, clinics, and other healthcare facilities. Although some reprocessors are affiliated with hospitals and health care facilities, many are independent companies. Accordingly,

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[21] *See, e.g.*, *Amicus* Br. of the United States at 2; *Amicus* Br. of Huawei Tech. Co., Ltd. at 8–9; *Amicus* Br. of Intel Corp., Dell Inc., and Vizio Inc. at 5.

[22] *Restatement (Second) of Contracts* § 302 (1981) (explaining that third parties to the contract have a basis for recovery only where they were an intended beneficiary); 1 Donald S. Chisum, *Chisum on Patents* § 16.01 (2015).

there is often no contractual privity between the patent owner and the reprocessor. Without contractual privity, the patent owner cannot enforce the single-use restriction under contract law. Even where contractual privity exists between the manufacturer and the reprocessor, contractual remedies may not provide the injunctive relief necessary to prevent improperly reconditioned single-use devices from entering the market.

Amici have also alleged that unless this Court establishes a bright-line patent exhaustion rule extinguishing a patent holder's rights after any sale made by the patent holder, consumers may become liable for every day occurrences, including selling a used car or having a garage sale.[23]

Such a possibility, however, is inherent in patent law, regardless of the outcome of the present case. Patent infringement is a strict-liability tort.[24] Thus, the potential for consumer liability for patent infringement exists with every patent. A consumer may unknowingly purchase a product from an infringer. Or a consumer may purchase a product from a licensee that has sold patented products outside the scope of its license. Such a consumer is liable for infringement,[25] though it is highly unlikely

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[23] *See Amicus* Br. of the Association of Medical Device Reprocessors at 17.

[24] *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1926 (2015).

[25] *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938).

that any patentee would find it worthwhile to pursue an ordinary consumer under these circumstances.

Amici have also argued that this Court should overrule decisions permitting post-sale restrictions because it would be unfair to enforce post-sale restrictions against third parties not involved in negotiating and agreeing to the original sales contract.[26] Such *amici* contend that, if post-sale restrictions are imposed on third parties, third parties will need to undertake costly investigations for each item in order to assess whether an item can be reused.[27]

The vast majority of single-use devices state directly on the product, its packaging, and/or its instructions, that the device is for a "single-use only."[28] Even if a used single-use device contains no restriction markings when received by a reprocessor, a basic investigation will inform a reprocessor as to whether the manufacturer restricted the device to a "single-use only." Reprocessors must conduct at least this level of investigation because they need to

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[26] *See Amicus* Br. of Intel Corp., Dell Inc., and Vizio Inc. at 12–13.

[27] *See Amicus* Br. of the Association of Medical Device Reprocessors at 19.

[28] *See Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 702 (Fed. Cir. 1992) ("The device is marked with the appropriate patent numbers . . . and the inscription 'Single Use Only'. The package insert provided with each unit states 'For Single Patient Use Only' and instructs that the entire contaminated apparatus be disposed of in accordance with procedures for the disposal of biohazardous waste.").

obtain all available information about the device prior to investing resources (including filing a FDA 510(k) statement) to recondition the device. Thus, even if the reprocessor is not a party to the original contract, the reprocessor is frequently on notice of any single-use restriction for the device. Moreover, medical device manufacturers could also affirmatively put reprocessors on notice by sending notifications directly to reprocessors identifying products not licensed for multiple uses. Thus, reprocessors would not be left guessing as to whether the patent owner licensed multiple uses.

In any event, the decision below would impose liability on the reprocessor only if it had notice of the single-use restriction.[29] This is consistent with this Court's prescendent requiring notice under similar circumstances.[30]

If this Court holds that the exhaustion doctrine renders all post-sale single-use restrictions ineffective, not only will medical device manufacturers be unable to bring patent infringement claims against third parties whose actions operate beyond the license granted, they will

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[29] *Lexmark Int'l, Inc. v. Impression Prods. Inc.*, 816 F.3d 721, 752 (Fed. Cir. 2016) (en banc), *cert granted*, 137 S. Ct. 547 (2016).

[30] *General Talking Pictures v. W. Elec. Co.*, 305 U.S. 124, 127 (1938) ("as Pictures Corporation [the consumer] knew the facts, it is in no better position than if it had manufactured the amplifiers itself without a license.")

also be unable to enforce ***any*** restrictions or guidelines for reprocessing their devices.[31]

The FDA has stated that "[r]educing the risk of exposure to improperly reprocessed medical devices is a shared responsibility among various stakeholders . . . [including] manufacturers, responsible for providing adequate reprocessing instructions that are user-friendly and proven to work."[32] If all post-sale restrictions are held ineffective, medical device manufacturers will be unable to ensure compliance with the guidelines for safely reprocessing reusable devices.

Amici also argue that the FDA has approved certain single-use medical devices for reprocessing, and allege that manufacturers label devices as "single use" to avoid submitting evidence supporting re-use to the FDA.[33] Despite the FDA's approval of certain reprocessed devices, manufacturers may still possess legitimate concerns that a device labeled for single-use cannot be reused without risking patient safety. While reprocessed devices may appear safe for re-use, testing of reprocessed devices may not uncover devices with decreased performance as a result of reprocessing.[34] Further, predicting failure

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[31] U.S. Food & Drug Admin., *Working Together to Improve Reusable Medical Device Reprocessing*, (2015), http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454626.htm.

[32] *Id.*

[33] *See Amicus* Br. of the Association of Medical Device Reprocessors at 11–12.

[34] *See* Eucomed Med. Tech., *supra* at 13, 37.

and performance of complex single-use devices may be difficult.[35] Thus, a device that complies with FDA safety regulations may be unknowingly compromised by the reprocessing process, resulting in unsatisfactory performance or failure of the device. Further, a manufacturer's reputation can be harmed by low quality reprocessed items.[36] Failures caused by reprocessing can be prevented by using the device in accordance with single-use restrictions. Manufacturers are in a unique position to recognize the potential dangers of reprocessed devices, and may label devices as single use to ensure patients are protected from easily avoidable harm, not as a means to avoid further FDA regulation. Indeed, as the FDA recognizes, not all devices are suitable for reprocessing.

C. Post-Sale Restrictions Are Consistent With This Court's Precedent

Medical device manufacturers rely on their ability to ensure compliance with post-sale use restrictions on patented devices through infringement actions, especially in light of the long tradition of permitting single-use restrictions. Nothing in the *Quanta* decision contradicts the basic premise that, within the limits of antitrust and misuse, patentees are free to grant any license scope they choose when selling a patented product. In *Quanta*, this Court analyzed the contents of the

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[35] *Id.* at 37.

[36] *Lexmark*, 816 F.3d at 752.

specific agreements between LGE and Intel, and held that the agreements did not contain any restrictions on Intel's ability to sell to any third parties. Because there were no restrictions on Intel's ability to conduct sales with any third party, *Quanta* did not implicate the conditional-sale doctrine. Further, single-use restrictions are consistent with this Court's precedent permitting patentees to separately transfer or license a subset of their patent rights, including the right to sell, use, and manufacture devices embodying a patent.

1. *Quanta* Did Not Overrule Post-Sale Restrictions

Although Petitioner contends that *Quanta* overruled all post-sale restrictions, *Quanta* did not address the precedent that expressly permits patentees to contract around the default patent exhaustion rule, despite invitations to do so from *amici*.[37] Concluding that *Quanta* established a "bright-line patent exhaustion doctrine," as other

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[37] *See e.g.*, Br. for the United States as *Amicus Curiae* Supporting Petitioners at 18–24, *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008); *see also* Amelia Smith Rinehart, *Contracting Patents: A Modern Patent Exhaustion Doctrine*, 23 Harvard J. L. & Tech. 483, 503 (2010) ("*Quanta* does not address the viability of *Mallinckrodt* or whether exhaustion doctrine should be considered immutable rather than the default rule."); *see also* Shubha Ghosh, *Carte Blanche, Quanta, and Competition Policy*, 34 J. Corp. L. 1209, 1226 (2009) ("The explanation for the absence is straightforward. The Court [in *Quanta*] is not overruling *Mallinckrodt*.").

amici have suggested,[38] misreads the holding of *Quanta*.

In *Quanta*, this Court held that LGE's patent rights were exhausted due to an unconditional sale.[39] In concluding that an unconditional sale occurred, *Quanta* looked to the licensing agreement at issue, and concluded that "[n]othing in the License Agreement restricts Intel's right to sell its microprocessors and chipsets to purchasers who intend to combine them with non-Intel parts."[40] This Court then reiterated that "[n]o conditions limited Intel's authority to sell products substantially embodying the patent."[41] Indeed, the license agreement expressly re-affirmed that ordinary patent exhaustion rules would apply to any sale.[42]

This Court therefore held that exhaustion applied because "[n]o conditions limited Intel's authority to sell products substantially embodying

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[38] *See Amicus* Br. of the Association of Medical Device Reprocessors at 21.

[39] *Quanta*, 553 U.S. at 636–37; *see also* William LaFuze, Justin Chen & Lavonne Burke, *The Conditional Sale Doctrine in a Post-Quanta World and its Implications on Modern Licensing Agreements*, 11 J. Marshall Rev. Intell. Prop. L. 295, 309–10 (2011) ("However, since the Court [in *Quanta*] based its ruling on the conclusion that the license agreement between LGE and Intel was unconditioned with regard to sales of Intel products, there was no need for the Court to address the conditional sale doctrine.").

[40] *Quanta*, 553 U.S. at 636.

[41] *Id.* at 637.

[42] *Id.* at 623 ("nothing herein shall in any way limit or alter the effect of patent exhaustion").

the patents," and therefore "Intel was authorized to sell its products to Quanta."[43] Thus, the license and unconditional subsequent sales by Intel exhausted LGE's patent rights because they were authorized, unrestricted sales, not because patent exhaustion is an immutable and unavoidable doctrine.

Moreover, *Quanta* suggested that valid post-sale conditions can be used by a patent owner to alter the default rule for patent exhaustion. Again, this Court specifically stated that, "[n]othing in the License Agreement restricts Intel's right to sell its microprocessors and chipsets to purchasers who intend to combine them with non-Intel parts."[44] *Quanta*'s focus on this fact suggests that, if a contractual restriction on the purchasers' rights had existed in the license to Intel, the outcome of *Quanta* may have been different.

It is also telling that *Quanta* avoided overruling *General Talking Pictures*.[45] Instead, *Quanta* distinguished *General Talking Pictures* from the facts presented in *Quanta*, stating that, unlike the license in *General Talking Pictures*, which restricted the customers to whom the licensee could sell products, LGE's license did not place any conditions on Intel's sales, and therefore Intel could

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[43] *Id.* at 637.

[44] *Id.* at 636.

[45] *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175, 181 (1938).

sell to any third party without restriction.[46] Thus, this Court specifically distinguished *Quanta* from *General Talking Pictures* by focusing on the absence of a restriction in the licensing agreement, instead of summarily concluding that *General Talking Pictures* should be repudiated. Again, this Court's focus on the absence of conditions in the agreements between LGE and Intel further suggests that, if valid restrictions had been present, LGE could have enforced its patent rights against Quanta. If *Quanta* intended hold that all post-sale restrictions imposed through contract are ineffective to alter the default exhaustion rule, there would have been no need to conduct a lengthy analysis of the contracts between LGE and Intel, because the contracts would have no effect on the result.

Petitioner argues *Quanta* overruled prior decisions permitting patentees to alter the default patent exhaustion rule, based on the statement that patent rights were exhausted by "the authorized sale of an article that substantially embodies a patent."[47] However, an "authorized sale" necessarily implies that the sale was either unconditional, or that the condition was met. If the sale was conditional and that condition was violated, the sale would not be "authorized." Interpreting "authorized" to merely require that the patent owner knew about and

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[46] *Quanta*, 553 U.S. at 636 ("[E]xhaustion did not apply because the manufacturer had no authority to sell the amplifiers for commercial use.") (citing *Gen. Talking Pictures*, 304 U.S. at 181).

[47] Br. of the Petitioner at 15-16 (quoting *Quanta* at 638).

accepted the sale at the time the sale was conducted substantially narrows the term beyond its natural meaning. This Court thus recognized that authorization may be conditional, and emphasized that "[n]o conditions limited Intel's authority to sell products substantially embodying the Patents."[48]

2. This Court's Other Precedents Are Likewise Consistent With Post-Sale Restrictions

The conclusion that single-use restrictions are not *per se* impermissible is also consistent with this Court's decisions prior to *Quanta*. While this Court has held that an "authorized" sale exhausts a patent owner's rights, this Court has never held that ***lawful*** post-sale restrictions are ineffective to retain some patent rights. The only such restrictions this Court has held ineffective involved illegal tying or price fixing.[49]

This Court has long recognized a patent owner's freedom to separately confer its rights to manufacture, sell, and use.[50] This Court has

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[48] *Quanta*, 553 U.S. at 637.

[49] *See United States v. Univis Lens Co.*, 316 U.S. 241, 250, 252-254 (1942) (condemning an agreement to "control the resale price of patented articles which he has sold," a type of "price fixing," that violated the Sherman Act). *See also Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917) (condemning a requirement that the patented product be used only with the patent owner's unpatented supplies).

[50] *United States v. Gen. Elec. Co.*, 272 U.S. 476, 490 (1926) ("The patentee may make and grant a license to another to

similarly held that a patentee's restrictions on the right to sell are valid "provided the conditions of sale are normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly."[51] Indeed, "the patentee may grant a license upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure."[52] This Court has also permitted patent owners to enter into restricted, conditional licenses that grant only limited authority to the licensee without exhausting all rights in the licensed patents.[53]

Contrary to arguments from various *amici*, this Court's decision in *Motion Picture Patents* did not hold that all post-sale restrictions are ineffective to prevent patent exhaustion.[54] In *Motion Pictures Patents*, a license notice attached to patented movie projectors stated that the purchaser had the right to

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make and use the patented articles, but withhold his right to sell them.").

[51] *Id.*

[52] *Gen. Talking Pictures*, 305 U.S. at 127 (quoting *Gen. Elec.*, 272 U.S. at 489).

[53] *Id.* at 126–27 (upholding enforcement of field-of-use restrictions through licenses divided between those who could sell for commercial purposes and those who could sell for home purposes); *Mitchell v. Hawley*, 83 U.S. 544, 549–50 (1873) (recognizing patent owner might grant manufacturer a license to make patented invention limited to the original patent term and expressly excluding any extension of the term).

[54] *See Amicus* Br. of Costco Wholesale Corp., LG Electronics Inc., Retail Litigation Center, Inc., SK Hyniz Inc., and Western Digital Corporation at 25–26; *Motion Picture Patents*, 243 U.S. at 502 .

use the machine only with motion picture films leased from the patentee.[55] The defendant used the patented machine with films leased from other sources.[56]

This Court held that the patentee's tie-in restriction was invalid because it extended the scope of its patent monopoly to unpatented products.[57] As this Court explained:

> [W]e are convinced that the exclusive right granted in every patent must be limited to the invention described in the claims of the patent, and that it is not competent for the owner of a patent, by notice attached to its machine, to, in effect, extend the scope of its patent monopoly by restricting the use of it to materials necessary in its operation, but which are no part of the patented invention.[58]

Thus, the decision in *Motion Picture Patents* did not extend beyond illegal tying, and is consistent with lawful restrictions on patent use which do not impermissibly extend the scope of a patent monopoly.

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[55] *Motion Picture Patents*, 243 U.S. at 506–07.

[56] *Id.* at 507.

[57] *Id.* at 518.

[58] *Id.* at 516.

Similarly, this Court's decision in *Univis* involved an unlawful price-fixing scheme that this Court held violated the Sherman Act.[59] This Court repeatedly emphasized that the patentee was attempting to "control the resale price of patented articles which he has sold."[60] This Court even described the patentee's conduct as a "price fixing" scheme that violated the antitrust laws.[61] Not surprisingly, the Court held that the patentee's unlawful restriction on pricing was unenforceable. The suggestion that *Univis* precludes lawful restrictions on the use of a patented device is simply unfounded.

Far more analogous to the present case is this Court's decision in *General Talking Pictures*.[62] There, the patent owner granted Transformer Company a license to make and sell amplifiers only for the residential market, not the commercial market.[63] In violation of this restriction, Transformer Company sold patented amplifiers to Pictures Corporation for commercial use.[64]

This Court upheld the patentee's right to sue both Transformer Company and Pictures

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[59] *Univis*, 316 U.S. at 252-55.

[60] *Id.* at 250. *See also id.* at 249 ("control the price"); *id.* at 251 ("control the price"); *id.* at 252 ("control the price").

[61] *Id.* at 252.

[62] *Gen. Talking Pictures*, 305 U.S. 124.

[63] *Id.* at 125-26.

[64] *Id.* at 126.

Corporation.[65] Writing for the Court, Justice Brandeis explained that "the patentee may grant a license 'upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure.'"[66] Because the restriction at issue "was legal," and the amplifiers were made and sold outside the scope of the license, "the effect is precisely the same as if no license whatsoever had been granted."[67] Accordingly, the patent owner was entitled to sue Transformer Company for patent infringement, along with Pictures Corporation which was aware of the restriction on Transformer Company's license.[68]

The single-use restriction at issue here is not distinguishable in any meaningful way. There is nothing unlawful about the restriction; there is no allegation that it violates the antitrust laws or constitutes patent misuse. As in *General Talking Pictures*, the patent owner has restricted a sale merely by declining to part with one of the many patent rights that the patent owner is entitled to sell or keep for itself. This "is reasonably within the reward which the patentee by the grant of the patent is entitled to secure."[69] Accordingly, as in *General Talking Pictures*, the patent owner is free to enforce its patent against the party who purported to sell more rights than it had acquired, as well as the

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[65] *Id.* at 127.

[66] *Id.* (quoting *Gen Elec.*, 272 U.S. at 489).

[67] *Id.*

[68] *Id.*

[69] *Id.*

subsequent purchaser, at least where that purchaser has notice of the restriction.[70]

3. The United States Creates An Unnecessary Distinction Between First Sales Made By Licensees, And First Sales Made By Patentees

In its October 12, 2016 brief in support of the grant of certiorari, the United States acknowledged that "no discrete provision [of the Patent Act] squarely forecloses the Federal Circuit's approach."[71] However, the United States argues that the Federal Circuit's reliance on *General Talking Pictures* was in error.[72] The United States argues that *General Talking Pictures* merely holds that a first sale made by a licensee in violation of the license terms is not an authorized first sale, and therefore does not trigger patent exhaustion.[73] The United States attempts to distinguish *General Talking Pictures* from the present case because Lexmark's first sale, although with conditions, was made by the patentee (which the United States interprets as an "authorized" sale), and thus the patentee exhausted all patent rights in the item post-sale.[74] The Government asserts that *General Talking Pictures* would be relevant to the present case only if a licensee in contract with Lexmark agreed to impose a

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[70] *Id.*

[71] Oct. 12, 2016 *Amicus* Br. of the United States at 9.

[72] Jan. 24, 2017 *Amicus* Br. of the United States at 20.

[73] *Id.*

[74] *See id.* at 19–22.

single-use/no-resale restriction on the cartridges, but failed to impose such a restriction on a third party buyer.[75] In this instance, the Government concedes that the third party buyer who resold or reused the cartridges would be liable for infringement.[76] Thus, the Government creates a distinction based on whether the patentee makes the first sale, or whether the patentee licenses the first sale.

As the Federal Circuit explained, that argument draws an unnecessary and meaningless distinction between a first sale occurring by a licensee, and a first sale occurring by a patentee. If all sales made by a patentee, regardless of restrictions, exhaust a patentee's §271 rights, patentees will be denied a right guaranteed to non-practicing patentees under *General Talking Pictures*.[77] This would give non-practicing entities greater power to maintain patent rights than practicing entities,[78] resulting in non-practicing entities with greater ability to decide and control which sales are "authorized."

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[75] *Id.* at 21.

[76] *Id.* at 22.

[77] *Lexmark*, 816 F.3d at 735, 744.

[78] *Id.* at 744.

D. Post-Sale Restrictions Permit Patent Owners To Efficiently Allocate Their Patent Rights

Patent rights have the characteristics of personal property.[79] The property rights conferred by a patent have been analogized to a bundle of sticks that patent owners are entitled to parse out as they see fit.[80] Thus, patent owners can sell distinct sticks from their bundle of property interests without including the remainder of their sticks.[81] As this Court held in *Adams*, patent owners may transfer the right to use or manufacture separately from the right to sell.[82] This allows patentees to efficiently

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[79] 35 U.S.C. § 261 ("[P]atents shall have the attributes of personal property."); *see also* Adam Mossoff, *A Simple Conveyance Rule for Complex Innovation*, 44 Tulsa L. Rev. 707 (2009).

[80] *Restatement (Second) of Contracts* § 721; Amelia Smith Rinehart, *Contracting Patents: A Modern Patent Exhaustion Doctrine*, 23 Harv. J. L. & Tech. 483, 495 (2010) ("A patent owner also can divide his bundle of rights to exclude others, separating the right to use from the right to sell the patented invention."); Leonard J. Hope, *The Licensed-Foundry Defense in Patent Infringement Cases: Time to Take Some of the Steam Out of Patent Exhaustion*, 11 Ga. St. Univ. L. Rev. 621, 625 (1995) ("A patent is considered, like other property, to be a bundle of rights.").

[81] *Gen. Elec.*, 272 U.S. at 489–90; *Adams v. Burke*, 84 U.S. 453, 456 (1873) ("The right to manufacture, the right to sell, and the right to use are each substantive rights, and may be granted or conferred separately by the patentee."); *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 875 (Fed. Cir. 1991) ("[Patent rights are] a bundle of rights which may be divided and assigned, or retained in whole or part.").

[82] *Adams*, 84 U.S. at 456.

grant a limited license of a scope that both parties desire, at a price to which both agree. In other words, at least some purchasers would view a product with a single-use restriction to be worth less to them than the same product with no such restriction. Accordingly, one would predict the limited nature of the license to be factored into the price.[83] Indeed, in this case, purchasers paid less for printer cartridges they agreed to return after a single use.

If all patent rights are conveyed with every sale, without exception, as the Petitioners claim, manufacturers will need to consistently charge higher prices in order to be adequately compensated for the conveyance of the entirety of their patent rights. As a result, hospitals and other health care providers may face increased costs for unnecessary rights.

Further, rendering patentees unable to convey only a subset of their patent rights in a product at the time of sale will not simplify transactions in the medical device industry. If post-sale restrictions are ineffective to alter the scope of the license conveyed with a sale, manufacturers may begin to institute more complex licensing structures to address patient safety. For example, manufacturers may impose contractual penalties to dissuade the transfer of used single-use devices.

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[83] *See B. Braun Med. Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997).

IV. CONCLUSION

The viability of single-use restrictions is not only warranted by this Court's precedent, it also enables medical device manufacturers to promote patient safety by restricting certain patented devices to a single use, and enforcing violations of that restriction against third parties in a patent infringement suit. Doctors, hospitals, device manufacturers, and patients benefit from the simplicity and flexibility of conditional sales. This Court should affirm the Federal Circuit's decision below.

Respectfully submitted,

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Paul A. Stewart
Counsel of Record
Joseph S. Cianfrani
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Fl.
Irvine, CA 92614
(949) 760-0404
Attorneys for Amicus Curiae Medical Device Manufacturers Association